510(k) Summary

Optovue, Incorporated
CA Model: CAM

SEP 28 2007

This 510(k) summary for the CA is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

General Information

Manufacturer:	Optovue, Inc. 41752 Christy Street, Fremont, CA 94538 Phone: (510) 623-8868 Fax: (510) 623-8668 Registration No.:
Contact Person:	Jay Wei CEO/President Optovue, Inc. Phone: (510)623-8868 x102 e-mail: jay_wei@optovue.com

Device Information

Classification:	Class II
Trade Name:	CA Model: CAM
Common Name:	Optical Coherence Tomography (OCT)
Classification Name:	Ophthalmoscope, a-c powered (21 CFR§ 886.1570)

Predicate Devices

RTVue (K062552) – Optovue
Visante OCT (K051789) – Carl Zeiss Meditec
Bioptigen (K063343) - Bioptigen Inc.

Intended Use

The CA, an auxiliary lens adapter, when used in conjunction with RTVue, is indicated for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye.

Device Description

The CA device uses the same Optical Coherence Tomography (OCT) technology that was previously reviewed by FDA in its clearance of premarket notification K062552 for RTVue. The CA adapter gives the user an option to use the RTUve device as previously approved for retina scans, or to use it for cornea and anterior eye scans. Aside from the CA auxiliary attachment, the RTVue is virtually unchanged for the CA use except the CA software module provides for menu selections in the graphical user interface, which are selected by the operator to label corresponding corneal landmarks instead of those of the retina. The system scans a beam into patient's eye and uses a low coherence interferometer to measure the reflectivity of the ocular tissue. The cross-sectional ocular tissue structure is composed of sequence of A-scans. RTVue has a traditional patient and instrument interface like most ophthalmic devices. The device is mounted on a motorized patient table. The patient will rest their head on the forehead and chin rest. The operator uses joystick to align the device to patient's eye. The computer has a graphic user interface for acquiring, analyzing and displaying the acquired image. The RTVue image acquisition speed and image resolution remain the same when used in conjunction with CA.

Safety

The energy level and all safety related design of the RTVue remains the same when used in conjunction with CA. The only difference is that the CA allows RTVue system to image the cornea instead of the retina. The addition of the CA does not change the safety.

Effectiveness

The image resolution of RTVue when used in conjunction with CA is 5um which is about 3 times better than the predicate device Visante OCT. The scan speed of RTVue when used in conjunction with CA is also 13 times faster than Visante OCT.

Substantial Equivalence

The RTVue/CA is substantially equivalent to the predicate devices presented within this premarket notification with regard to intended use, operating principle, function, material, and energy source, all of which are similar. The RTVue/CA can perform imaging on cornea and anterior segment by simply adding a lens in front the existing RTVue ocular lens. The indication of use on the cornea and anterior segment of the eye are equivalent to another predicate device, Visante OCT marketed by Carl Zeiss Meditec and to that of Bioptigen Inc. All these devices are based on the same Optical Coherence Tomography technology.

Performance Test Data

Non-Clinical:

Image Resolution Test:

Objective: To measure the axial resolution of RTVue/CA

Result: The axial resolution of the tested RTVue/CA system is 5.1± 0.4μm

Clinical:

1. Corneal Imaging Comparison:

Objective: To compare images of cornea obtained with the RTVue/CA and with the Visante OCT.

Result: The RTVue/CA is capable of providing images that compare well with the Visante OCT. Anatomic features of the anterior segment of the eye were visible to the physicians that assessed the RTVue/CA images; the same physicians could not identify these features in the Visante OCT images.

2. Cornea Thickness Measurement Comparison:

Objective: To compare the cornea thickness measurement with other commercial available pachymeters.

Result: The cornea thickness measurement made by RTVue/CA is highly correlated with the ultrasound pachymetry system (Pearson correlation r = 0.9889), Orbscan II (Pearson correlation r = 0.9995), and Visante OCT (Pearson correlation r = 0.9924 at the vertex, r = 0.9939 over the central zone). The reproducibility of the RTVue/CA corneal measurement was 1.2 μm root-mean-square for the difference between repeat pachymetry maps.

Conclusion

As described in this 510(k) Summary, all testing and analysis were conducted on the RTVue/CA to ensure that the device is safe and effective for its intended use when used in accordance with its instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Optovue, Inc.
c/o Jay Wei
41752 Christy Street
Freemont, CA 94538

SEP 28 2007

Re: K071250
Trade/Device Name: CA
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: August 22, 2007
Received: August 23, 2007

Dear Mr. Wei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

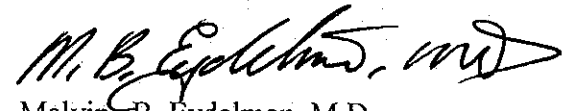
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CA Model:CAM

Indications for Use:

The CA, an auxiliary lens adapter, when used in conjunction with RTVue, is indicated for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R. Ruttenberg

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K071250